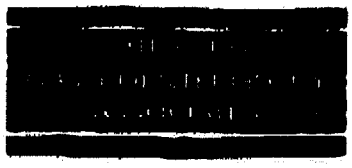

November 15, 2000

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Dear Colleagues:

So often in our society, we are willing to criticize, but not commend. This letter is in regard to the commendation of your approval of the drug, Lotronex.

I am a gastroenterologist in a single specialty group in Atlanta, Georgia with 21 physicians within the group. It is my special duty within this group to take care of the patients who have gastrointestinal motility disorders or functional bowel syndrome. Within that spectrum falls a group of disorders known as irritable bowel.

In particular, I lauded the FDA earlier this year at the time of the approval of the drug, Lotronex. In 20 years, we had not seen a medication that was not merely direct toward symptoms, but was directed toward the physiology of a condition. In fact, during my lectures on irritable bowel syndrome, any physician that you would speak to would know the list of medications that are available for this disorder. The drugs that we had prior to the Lotronex were somewhat effective, but as I described to you, were only so in that they treated symptoms.

The patient's I see are not the "normal" patients. I see many patients who have gone to other tertiary care centers for evaluation, including such institutions as the Mayo Clinic, Cleveland Clinic, or Duke University. I gladly send these patients there for a second opinion and sometimes they have difficulty understanding a condition that has no inflammatory activity, discernible x-ray abnormality, or perturbed blood parameter.

I am sure you have heard multiple anecdotes, but there are several that I would like to relate to you from a personal level. First of all, I would like to say to you that I have several patients in my practice who have required narcotic analgesia for control of their condition.

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One particular patient takes 75 mcg of Duragesic to control her diarrheal symptoms to the point where she is able to perform her daily household activities. With the approval and implementation of Lotronex for this patient, her life has changed dramatically. She has basically been weaned off of these types of medications and takes an occasional teaspoonful of paregoric to control her symptoms. This is a Lotronex success.

I also have a patient who is a trial lawyer who, due to the multiple sedating properties of both anticholinergic drugs and narcotic analgesics, was about to change careers. She was not able to perform trial law any longer. With the utilization of Lotronex, this lady has returned to the legal workplace in her chosen vocation.

Regarding the side effects described, since implementation, our group has prescribed 5,000 prescriptions. There has been no fatality in these prescriptions and no episode of ischemic colitis has been described. Our group also participated in the original studies leading up to the FDA approval.

I must say that, unfortunately, I think some of the adverse reactions that we see with drugs like Lotronex are not related to the drug itself. I feel that in a significant number of these situations, there may be physician responsibility. What I mean by this is that sometimes patients are not selected appropriately for utilization of a drug. As you are well aware, there is a particular role for this drug in diarrhea-predominant irritable bowel syndrome (D/IBS). This drug is effective and should be allowed to remain as a weapon in the armamentarium against functional bowel disorders.

In summary, this is a letter of support for the product, Lotronex, which has saved so many lives of the patients in my practice that is dedicated toward treatment and diagnosis of irritable bowel/ functional bowel disorders. Removal of this product from the market place would be the travesty for the 4.5 million individuals in this country who suffer from irritable bowel syndrome.

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Thank you for your attention to this matter in advance.

Sincerely,

Dirk P. Siaker, M.D.
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